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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,719	10/10/2001	Frederick M. Ausubel	00786/361003	1062

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,719

Applicant(s)

AUSUBEL ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 44-53 is/are pending in the application.
- 4a) Of the above claim(s) 1, 44-47 and 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48, 49 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2005 has been entered.

Accordingly claims 1, and 44-53 are pending in the instant application, of which claims 1, 44-47, and 50-52 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 48-49 and 53 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants are asserting that the claims have been amended to recite that the polypeptide is a virulence factor. Applicants further assert that

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SEQ ID NO: 252 encodes a single polypeptide of 640 amino acids, and that while multiple start codons are in fact present in SEQ ID NO: 252, one skilled in the art would recognize that SEQ ID NO: 252 encodes one open reading frame that encodes a full length polypeptide. Applicants further assert that SEQ ID NO: 252 encodes one open reading frame that encodes a full length polypeptide, and Applicants' claims have been amended accordingly.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants are asserting that the claims have been amended to recite that the polypeptide is a virulence factor, encodes a single polypeptide of 640 amino acids, and contains only one reading frame. However, amendment to recite that the polypeptide is a virulence factor, does not remedy Applicants lack of sufficiently describing the polypeptide in the first place. As stated previously, Applicants SEQ ID NO: 252 contains multiple start and stop codons, and despite Applicants unsupported arguments to the contrary, one of skill in the art would not immediately recognize one and only one full-length open reading frame. Applicants are again asked to explain how one of skill in the art would be lead to nucleotide numbers 19-

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21 of SEQ ID NO: 252 as the only full length open reading frame, when there is also a start codon at positions 7-9, in the identical reading frame? Furthermore, why would other start codons in other reading frames be ignored? While Applicants continue to assert that there is only one open reading frame, the specification does not, at the time of filing, identify this region.

Furthermore, Applicants assert that the claimed polypeptides are distinguished from other polypeptides by both the structural characteristic and functional characteristic of being a virulence factor.

However, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number** of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” (Emphasis added). Simply stated, Applicants disclosure of an unidentified reading frame of nucleotides does not provide sufficient support for the broadly claimed genus of any polypeptide having “90%” identity to an undescribed polypeptide in the first place.

Claims 48-49 and 53 are directed to a substantially pure polypeptide comprising an amino acid sequence that has at least 90% identity to the amino acid sequence of the full length polypeptide encoded by SEQ ID NO: 252, wherein said polypeptide is a virulence factor.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 252 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Furthermore, Applicants have claimed a protein encoded by SEQ ID NO: 252 without identifying a full length open reading frame. The isolated DNA strand (SEQ ID NO: 252) has multiple reading frames, Applicants have not identified a start codon or a stop codon of the protein being

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claimed. Consequently, Applicants have not identified a function which identifies members of the genus, since the structure of the protein cannot be fully determined without a start and stop codon for the full length protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

Claim Objections

2. The objection of Claim 48 for reciting "... has a least 90% identity.... An obvious typographical error, is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

3. Claims 48-49 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 48-49 and 53 have been amended to recite "the full length polypeptide encoded by SEQ ID NO: 252." However, Applicants at the time of filing, did not identify the open reading frame of SEQ ID NO: 252, consequently any attempt to now determine the reading frame and the resulting "full length polypeptide encoded by SEQ ID NO: 252" is deemed new matter. Applicant is required to demonstrate clear support (page and line number of the specification) showing the full length open reading frame of SEQ ID NO: 252, or cancel the newly added limitation.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
July 28, 2005